FPC Fair Pricing Coalition

February 19, 2016

The Honorable Ron Wyden
The Honorable Chuck Grassley
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510-6200

RE: Gilead Report Responses

Dear Senators Wyden and Grassley:

Pursuant to the January 21, 2016 request for feedback regarding your Gilead Report, below please find responses from the Fair Pricing Coalition (FPC).

Let me take this opportunity to once again thank you for your excellent and very comprehensive Pulitzer Prize worthy report.

Respectfully yours,

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1. **What are the effects of a breakthrough, single source innovator drug on the marketplace?**

Medicare and Medicaid are at the mercy of unconscionable pricing decisions which may result ever more frequently as new research continues in diseases like cancer, Alzheimer's disease, and diabetes.

Without new legislation, most drug companies will invariably charge what the market will bear for breakthrough, single source innovator drugs, as there is no reason or incentive to do otherwise. The longer it takes for market competition to address the situation as in the Gilead Sciences (Gilead) vs AbbVie hepatitis C (HCV) scenario, the less access there will be for patients, and the longer Medicare and Medicaid price gouging will occur. This will result in budget busting costs for public payers, including federal correctional health service providers, and a vicious circle of even less patient access to potentially life-saving drugs.

While Medicaid programs and Medicare Part D plans are able to individually negotiate with manufacturers, negotiations would be significantly more effective if the purchasing power of both groups was centralized. Legislation that authorizes the Centers for Medicare and Medicaid Services to negotiate on behalf of all Medicare plans and all Medicaid programs is essential to both patient access and to addressing federal and state budget concerns.

Legislation that requires additional and/or tiered rebates to government payers in certain cases defined by statue is also essential to this process. A legislative definition of what a breakthrough, single source innovator drug is and a formula for mandated rebates should be developed, based on items such as the proposed cost of the drug, the number of patients involved and the benefit of the breakthrough, single source innovator drug.

In the alternative, we also support higher discounts for brand-name drugs for seniors trapped in the Medicare coverage gap by raising manufacturer rebates from 50% to 75% in 2018, and the alignment of rebates for beneficiaries dually eligible for Medicaid and Medicare with the drug rebates required for the Medicaid program.

2. **Do the payers in the programs have adequate information to know the cost, patient volume, and increases in efficacy of a new treatment regimen?**

Initially, we believe that nothing in any new legislation in this regard should interfere with the drug approval process.

It is axiomatic that payers be required to have adequate knowledge about the costs, expected patient volume and increases in efficacy and/or better side effect profiles. It is evident from the Sovaldi and Harvoni cases that Gilead had limited pre-FDA approval interactions with an insufficient number of payers. Manufacturers typically avoid these interactions out of concern that they may violate prohibitions on the marketing of non-approved drugs. A safe harbor should be created to allow manufacturers to discuss anticipated FDA approvals with payers to prepare for expected costs and utilization, without violating pre-approval marketing prohibitions. New legislation should define permissible topics to be addressed during pharmaceutical negotiations with public payers involving breakthrough, single source innovator drugs, such as proposed costs, expected patient volume and increases in efficacy and/or better side effect profiles.

Legislation should also be enacted that will require drug companies to enter into good faith price negotiations and require additional/tiered rebates for Medicare and Medicaid as well as Medicare and Medicaid managed care programs and federal correctional health providers in certain defined cases where it is expected that a high percentage of people will likely be prescribed the breakthrough, single source innovator drug. This would mirror certain provisions of the Department of Veterans Affairs (VA) purchasing program, which requires companies both to offer calculated discounts on drugs as well as to negotiate certain aspects of the pricing calculation, resulting in substantial savings. The new legislation should also define the number/percentage of patients required to trigger negotiations that should include discussions of proposed costs, expected patient volume and increases in efficacy and/or better side effect profile as well as additional/tiered rebates.

Both patients and drug companies will benefit under this system, which will increase the volume of patients with access to the breakthrough, single source innovator drug through more formulary inclusion and preferred drug tiering, resulting in greater revenue to the company. Financial penalties should also be prescribed by statute for non-compliance with the provisions of any such new legislation.

3. **What role does the concept of "value" play in this debate, and how should an innovative therapy's value be represented in its price?**

Better safety, efficacy and outcomes profiles and to a lesser extent, ease of administration should be seen as value enhancements. While cost-effectiveness should also be considered as a measure of value, the determination of the final price should be weighed against the possible budget-busting effect of high costs that will be incurred if large patient populations will be using the new drug. Cost-effectiveness evaporates when a drug is unaffordable to patients and causes unsustainable prices for payers. In effect, the cost-effectiveness argument posited by

Gilead, comparing the price of a pharmaceutical cure to treatment costs for cirrhosis, liver cancer and/or a liver transplant actually resulted in an exorbitant pricing scheme that resulted in less access for patients, in spite of tremendous budget outlays by public payers. Less patient access precludes any long-term cost effectiveness if the morbidity and mortality the drug can prevent actually occurs as a result of pricing decisions that make the new drug unaffordable to patients and reimbursement unsustainable by payers. Less patient access to innovative therapies targeting infectious diseases may also reduce controlling or eliminating transmission of the infectious agent, negatively impacting the value of the drug at a community public health level.

Legislation should be crafted that defines a breakthrough, single source innovator drug with respect to specific safety, efficacy and long-term outcomes morbidity and mortality. Such legislation should also require drug companies to negotiate prices and require additional/tiered rebates for Medicare and Medicaid as well as Medicare and Medicaid managed care programs in certain defined cases where it is expected that a high percentage of people will likely need the breakthrough, single source innovator drug. This should also be considered for federally funded correctional health service providers to ensure access for incarcerated persons. The legislation should also define the number/percentage of patients required to trigger negotiations that should include discussions of proposed costs, expected patient volume and increases in efficacy and/or better side effect profile as well as additional/tiered rebates.

Some new drugs will be used by large populations, like people with HCV, but other disease groups, like specific cancer populations, may not. It is essential to address patient affordability and payer reimbursement sustainability for both patient populations. Although some cancers do not affect millions of people as does HCV, the cost of many cancer therapies, including biologics, for small populations have been astronomically priced for many years. Thus, any new legislation that defines a breakthrough, single source innovator drug with respect to specific safety, efficacy and long-term outcomes morbidity and mortality must also address historically exorbitant prescription drug costs for certain diseases, negotiations and additional/tiered rebates for exorbitantly priced drugs that will be used by small patient populations as well.

We also support President Obama's new 2017 CMS budget proposals to increase access to generic drugs and biologics by stopping companies from entering into anti-competitive deals intended to block consumer access to safe and effective generics, by awarding brand biologic manufacturers seven years of exclusivity, rather than 12 years under current law, and by prohibiting additional periods of exclusivity for brand biologics due to minor changes in product formulations.

4. **What measures might improve price transparency for new higher-cost therapies while maintaining incentives for manufacturers to invest in new drug development?**

New legislation should be crafted that allows manufacturers to charge prices that accurately reflect actual drug development costs, not including marketing or capital use costs. Manufacturers should be able to disclose drug development costs without disclosing confidential, proprietary information with respect to the actual scientific development of a drug. We believe that manufacturers refuse to disclose this type of information because excessive profits would also be disclosed. Federal drug payment for VA programs already require manufacturers to disclose sales data as a precondition for payment. Additional manufacturer data disclosure should be required for all other federal programs when prices meet certain thresholds. Any new legislation should forbid companies from receiving credit for development costs actually incurred by the NIH or other government entities. Marketing, capital use and other such costs should also be differentiated from true research and development costs.

Companies that are willing to disclose development costs would be eligible to charge commensurate prices as defined by statute. The ability to charge higher prices based on actual drug development costs will be an incentive for manufacturers to disclose development costs.
Financial penalties should also be prescribed by statute for inaccurate and fraudulent information provided by manufacturers with respect to any such new legislation.

At a minimum, the prices individual payers actually pay for drugs should be public information. Making these agreements public will help to drive down prescription costs by fostering competition, making drugs more affordable and ultimately sustainable in the long term.

We also support President Obama 2017 CMS budget proposal, supporting a drug "transparency" policy which would subject drug manufacturers to levels of transparency similar to insurers. We believe a transparency policy is an important step that should be accompanied by a policy that will limit drug company profits based on actual development costs, not including marketing and capital use expenditures or credits for development costs actually incurred by the NIH or other government entities. A system where costs are based on actual developmental expenses will reduce public payer spending.

5. **What tools exist, or should exist, to address the impact of high cost drugs and corresponding access restrictions, particularly on low-income populations and state Medicaid programs?**

Many restrictive prior approval cost containment measures were initiated by state Medicaid programs as a result of the exorbitant Gilead Sovaldi and Harvoni pricing. We believe that the federal and state government have ample tools necessary to address continued budget strains and to manage their patient populations. If anything, in light of new market discounts occasioned by FDA approval of newer HCV drugs such as AbbVie's Viekira Pak and Merck & Co.'s Zepatier, HCV drug formulary restrictions should be reviewed more than once annually in an effort to increase access to patients in situations where public payers are now paying much less for HCV treatments then was the case before the newest HCV drugs came to market.

We also support the president's 2017 other new CMS budget proposals aimed at reducing drug prices, including letting CMS partner with states to negotiate down drug prices, making drug makers disclose discounts and research-and-development costs, requiring drug wholesalers to report wholesale acquisition costs, requiring evidence development for Part D drugs, creating a Medicare Advantage bidding program, and eliminating surprise out-of-network charges in commercial plans. Currently, states are allowed to negotiate supplemental drug rebates, but CMS is not allowed to facilitate negotiation with drug makers. The President's proposal would allow CMS and state Medicaid programs to partner with a private sector contractor to negotiate supplemental rebates.

We also support various states joining together to create partnership entities to negotiate prices with drug companies. Legislation should be created to incentivize such state partnerships. Both options will provide states with more leverage than currently present with any one state.

President Obama has also proposed using coverage with evidence development in Medicare Part D, similar to the evidence development process in Parts A and B. We support further clinical trials and other data collection to support the appropriate use of drugs in Medicare patients and other relevant CMS identified populations. Finally, we have called for new legislation within the framework of the questions posed by the Senate Finance Committee. Although we stand by our recommendations under the circumstances, they nevertheless present a convoluted approach to dealing with a burgeoning budget busting, life-threatening unsustainable scenario that often makes treatment unaffordable to patients.

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We strongly believe that other remedies like federal legislation that limits out of pocket (OOP) prescription costs are necessary to assist patients with ever-increasing unaffordable OOP prescription drug costs, and that allows Medicare and Medicaid patients on brand name drugs without generic equivalents to enroll in drug company co-pay programs. Further, a single payer insurance program such as Medicare, and price controls for prescription drugs similar to those mandated in Western Europe would be optimal given the arguably insurmountable prescription drug development and reimbursement system crisis currently facing our country. Both the drug development and prescription drug reimbursement systems are irreparably broken. We need bold new comprehensive ideas, not the same old ideas that continue to provide the house of cards band aid approaches that have brought us to the untenable situation we find ourselves in today.

Respectfully submitted,

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